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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,478	09/10/2003	Carl E. Yee	BSI-260US3	3432

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RATNERPRESTIA
P O BOX 980
VALLEY FORGE, PA 19482-0980

EXAMINER

HILL, GENEVIEVE A L

ART UNIT PAPER NUMBER

3738

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/659,478	Applicant(s) YEE, CARL E.	
	Examiner Genevieve A-L. Hill	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-66 is/are pending in the application.
- 4a) Of the above claim(s) 48, 50, 51, 54, 55, 58 and 60-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-45, 47, 52 and 53 is/are rejected.
- 7) ☒ Claim(s) 46, 49, 56, 57 and 59 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/10/03 & 12/11/03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I (claims 42-60) and Species I (Figure 3A: claims 42-47, 49, 52-53, 56-57, and 59) in the reply filed on February 27, 2006 is acknowledged.
2. Claims 48, 50-51, 54-55, 58 and 60-66 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected species and groups, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on February 27, 2006.
3. This examination is based on claims 42-47, 49, 52-53, 56-57, and 59.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the following must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.
 - a. *In the expanded configuration, show the uncovered and covered portions of the stent as stated in claim 52*
 - b. *Third member as stated in claim 53*
5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "20" has been used to designate both lumen and walls in Figure 7D.

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6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: *reference character 78*.

7. The drawings are objected to because of the following:

- a. In Figure 3A, the line pointing to the suture 68 is inaccurate
- b. In Figures 7C-7D, the line pointing to the graft 50 is inaccurate

8. For all objections above, corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

9. Claim 42 is objected to because of the following informalities: lines 4 and 7 read “a free end” but is suggested to read –an opposite end—. Appropriate correction is required. *See 35 USC 112 rejection below.*

10. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. *See 37 CFR 1.75(d)(1) and MPEP § 608.01(o).* Correction of the following is required: definition in the specification of the connected end, free end, first member, second member, third member, and movable member.

11. Claim 52 objected to because of the following informalities: line 3 reads “covered by the *stent*” which is contradictory to the beginning of the claim. The Examiner believes the Applicant meant to write –covered by the *graft*--. Appropriate correction is required.

Claim Rejections - 35 USC § 112

Claims 42-47, 49, 52-53, 56-57 and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d

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1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "free end" in claim 42 is used by the claim to mean "retained by the second, non-sheath member", while the accepted meaning is "not constrained." The term is indefinite because the specification does not clearly redefine the term. In line 4 of claim 42, the Examiner interprets the end to be free meaning not constrained, but in line 7, the free end is retained in a compressed configuration and is therefore no longer free. See *MPEP 2111.01*.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 42-44, 47, and 52-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Galdonik et al (US Application 2003/0109887) in view of Lau (US Patent 6001123). Galdonik et al disclose a device in Figure 7 having a stent 10, graft 104, first member 92, and second member 70. The graft 104 has an end 37 connected to the stent 10 and the other end is free. The first member 92 releasably retains a portion of the stent 10 in a compressed configuration. But the second member 70 does not compress the free end of the graft 104. However, Lau teaches a stent-graft 310 in Figure 15A that is in a compressed configuration by a second, non-sheath member 306/308. It would have been

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obvious to one having ordinary skill in the art at the time the invention was made to modify Galdonik's device to include a second, non-sheath member in order to compress the graft since such a modification allows for control over expansion and compression of the graft (column 27, lines 33 and 59).

For claim 43, the first member 92 is a sheath (paragraph 55). Referring to claim 44, prosthesis is self-expanding (paragraph 34). Regarding claim 47, the second members are sutures (paragraph 49). For claim 52, Figure 6a shows the end 114 of the graft 104 is tied to the stent 10 and therefore leaves covered and uncovered portions of the stent even in an expanded configuration (paragraph 50). For claim 53, the third member 88/90 as shown in Figures 7 and 8 releasably retains the uncovered portion (the end near 86) of the stent 10 (paragraph 53).

14. Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Galdonik et al in view of Lau and Parodi (US Patent 5954764). Galdonik and Lau teach the device according to the rejection above, but, when referring to claim 45, they do not teach a first member in between a stent and graft. However, Parodi teaches a stent 12" and graft 13" with an inner sheath 15 between them. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Galdonik/Lau's device to include an inner sheath between the graft and stent since such a modification would resolve the irregular expansion of the prosthesis due to the different expansion properties of the stent and graft (column 2, lines 7-12).

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Allowable Subject Matter

15. Claims 46, 49, 56-57, and 59 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion


16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Genevieve A-L. Hill whose telephone number is (571) 272-7226. The examiner can normally be reached on Monday through Friday from 9:00am to 5:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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GAH



David H. Willse
Primary Examiner